

REMARKS

As an initial matter, Applicants thanks Examiner Isabella for the courtesies extended in the telephonic interview of July 30, 2003 in which the patentability of claims 1-5 in view of U.S. Patent No. 5, 019,090 and U.S. Patent No. 4,937,323 were discussed. Applicants primary argument was that these references do not teach or suggest a biodegradable material internally reinforced with biodegradable reinforcing elements.

With respect to the present amendment, claims 1, 2 and 5 have been amended, claim 3 has been canceled and claims 6-12 have been added. Therefore upon entry of the present amendments, claims 1, 2, and 4-12 will be pending in the present amendment.

Claims 1, 3, 4, and 5 stand rejected under 35 U.S.C. §102(e) as being allegedly anticipated by U.S. Patent No. 5,019,090 to Pinchuk ("Pinchuk"). Claim 2 stands rejected under 35 U.S.C. §103(a) as being allegedly rendered obvious by Pinchuk in view of U.S. Patent No. 4,937,323 to Silver *et al.* ("Silver"). Applicants respectfully traverse these rejections.

Claims Are Not Anticipated by Pinchuk

According to the Office Action, Pinchuk discloses a surgical implant comprising a biodegradable material wherein the material is reinforced in a longitudinal direction and the implant has a helical configuration. To support this assertion, the Office Action cites col. 7, lines 5+ which, according to the Office Action, provides for a stent that may be biodegradable and coated and that such disclosure is interpreted as disclosing an outer coating reinforced with a core of material.

With respect to claims 1, 2, 4, and 5, these claims have been amended to recite a "biodegradable material comprising a uniaxially or biaxially oriented polymer." Support for this amendment can be found, *inter alia*, on page 8, line 24 to page 9, line 2. An oriented polymer is a polymer that has underwent the process of orientation. As is known to one of skill in the art of polymer chemistry and as is explained in detail in the specification (*e.g.* page 10, line 18 to page 16, line 10), orientation is a process whereby a polymer structure is drawn to orient the molecular chains of the polymer in the drawing

direction. As stated on page 10, lines 20-22, "as a . . . polymer is being drawn, the molecular chains of crystal lamellae quickly begin to parallel, or orient, themselves in the drawing direction." There is absolutely no mention of a biodegradable material comprising a uniaxially or biaxially oriented polymer in Pinchuk and therefore claims 1, 2, 4, and 5 are not anticipated by this reference.

With respect to Silver, it is Applicants' position that claims 1, 2, 4, and 5 are also not rendered obvious by Pinchuk in view of Silver. As the Examiner is well aware, in order to establish a *prima facie* case of obviousness, there must be some motivation either in the references themselves or in the knowledge generally available to one of skill in the art to combine the teachings of the references to produce the claimed invention and the combined references must teach each and every element of the claims.

It is Applicants' position that there is no motivation to combine the teachings of Silver, which is directed to dressing a wound with a biocompatible biodegradable tissue product and applying electrical current to the product, with the teachings of Pinchuk, which is directed to a radially expandable stent for cardiovascular procedures. Further, the combination of Pinchuk and Silver does not teach each and every element of the recited claims. In particular, Silver discusses biaxial orientation of collagen fibers in the direction of the electrical field as current is applied to the collagen. This is not encompassed by a reasonable interpretation of the phrase "a biodegradable material comprising a uniaxially or biaxially oriented polymer," which refers to drawing a polymer to orient the molecular structure of the polymer. Accordingly, claims 1-5 are not rendered obvious by Pinchuk in view of Silver.

With respect to claims 6-12, these claims recite a surgical implant comprising biodegradable material internally reinforced with "biodegradable reinforcing elements." As described in detail in the specification, particularly on page 9, lines 3-9, "biodegradable reinforcing elements" can be "biodegradable organic filaments, fibers, membrane fibers or the like, or structures constructed thereof, such as bands, braids, yarns, fabrics, non-woven structures or the like, or biodegradable inorganic (ceramic) filaments, fibers, membrane fibers or the like or structures constructed thereof."

It is Applicants' understanding that based on the last Office Action, the Examiner is interpreting Pinchuk as disclosing an outer coating reinforced with a core of material and therefore will equate the outer coating with the "biodegradable material" of claims 6-12 and will equate the stent which the coating covers as "biodegradable reinforcing elements." It is Applicant's initial position that Pinchuk's coated stent is not the same as a biodegradable material internally reinforced with biodegradable reinforcement elements, as recited in claims 6-12 for at least the following reasons.

First, Applicants respectfully submit that it is unreasonable to interpret the term "biodegradable reinforcing elements" in a manner that renders the claims anticipated by any reference that describes a biodegradable material (*i.e.* stent) underlying another material (*i.e.* an outer coating). Applicants are well aware that during patent examination, claims must be given their broadest interpretation but such an interpretation must be reasonable. Furthermore, although the PTO is not required in the course of prosecution to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit, the Federal Circuit has held that "the PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification. *In re Morris*, 127 F.3d 1048 (Fed. Cir. 1997). Therefore, claims are "not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their broadest reasonable interpretation." *In re Marosi*, 71 F.2d 799 (Fed. Cir. 1983). The present application states on pages 8-9:

In the context of the present invention, the biodegradable reinforcing elements refer to the following:

- a) oriented or aligned structural units included in the micro-structure or molecular structure of a material such as oriented parts of molecules or parts thereof or microfibrils, fibrils, or the like oriented structural units formed thereby;
- b) biodegradable organic filaments, fibers, membrane fibers or the like or structures constructed thereof, such as bands, braids, yarns, fabrics, non-woven structures or the like; or
- c) biodegradable inorganic (ceramic) filaments, fibers, membrane fibers or the like, or structures constructed thereof.

Based on this description in the Applicants' specification, Pinchtuk does not teach or suggest a biodegradable material internally reinforced with biodegradable reinforcement elements. In particular, there is no mention in Pinchuk of organic or inorganic fibers or filaments, and more specifically biodegradable organic or inorganic fibers or filaments that internally reinforce a biodegradable material.

Furthermore, the biodegradable reinforcing elements of claims 6-12 are recited as "internally" reinforcing the biodegradable material. The stent of Pinchuk underlies the coating and does not "internally" reinforce the coating.

With respect to Silver, as mentioned above, there is no motivation to combine the teachings of Silver with the teachings of Pinchuk to produce a biodegradable material internally reinforced with biodegradable reinforcing elements.

Furthermore, notwithstanding whether the Examiner's interpretation of the claim term "biodegradable reinforcing elements" is reasonable, Pinchuk does not teach or suggest a biodegradable material that is reinforced with biodegradable reinforcing elements, as recited in claims 6-12. In particular, even if the stent described in Pinchuk is interpreted as "biodegradable reinforcing elements," the stent is not reinforcing a biodegradable material since there is no teaching or suggestion in Pinchuk of the outer coating being biodegradable.

Accordingly, Applicant submit that Pinchuk does not anticipate claims 6-12 as Pinchuk does not teach or suggest biodegradable reinforcing elements and does not teach or suggest a biodegradable material that is internally reinforced with such elements. Furthermore, claims 6-12 are not rendered obvious by Pinchuk in view of Silver because there is no motivation to combine these two references.


CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees are required in connection with the filing of this response, such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
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